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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/578,719	05/09/2006	Cheong-Ho Chang	P6106/Namy	3405

41943 7590 06/07/2011

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EXAMINER	
HANLEY, SUSAN MARIE	
ART UNIT	PAPER NUMBER
1653	
MAIL DATE	DELIVERY MODE
06/07/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/578,719	CHANG ET AL.
	Examiner	Art Unit
	SUSAN HANLEY	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5 and 6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 5 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1, 5 and 6 are pending.

Election/Restriction

Applicant's election of group I, claims 1 to 6 in the reply filed on 02/02/2010 is again acknowledged. Withdrawn claims 7-12 have been cancelled by amendment.

Applicant's election without traverse collagen as the elected species in the reply filed on 03/26/2010 is again acknowledged.

Claims 1, 5 and 6 are under examination.

Withdrawal of Rejections

The response and amendment filed 11/12/2010 are acknowledged. The rejections not explicitly restated below are withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Response to Arguments

Claim Rejections – 35 USC § 112

Claim 5 stands rejected under 35 U.S.C. 112, second paragraph. The claim was rejected because the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

Applicants argue that the claim has been amended to cancel the phrase.

The rejection stands because the phrase has not been cancelled.

The remainder of Applicant's arguments regarding the prior art rejections center on the new concentration range recited for thrombin which is not recited in the

previously cited prior art. The obviousness of this new limitation, as well as being New Matter, are addressed in the following rejections.

New Grounds of Rejection Necessitated by Amendment

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5 and 6 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Independent claim 1 has been amended to include the limitations of cancelled claim 2 and 3 as well as a new limitations for the concentration of thrombin, more than 2 IU/mL but less than 50 IU/mL This new range limitation is NEW MATTER.

The specification (p. 9) and the claims (original claim 3), both as filed, teach that the concentration of thrombin is 0.01 to 50 IU/mL The specification also teaches at pages 15 that the concentration of thrombin can be 1 IU/mL to 10 IU/mL. The specification does not disclose that the concentration range of thrombin is more than 2 IU/mL and less than 50 IU/mL.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Passaretti et al. (2001) in view Nevo et al. (US 4,642,120; new reference) and Liu et al. (US 5,972,385). The rejection basis of claim 5 is maintained in the next rejection but not maintained in the instant rejection.

Applicant claims a composition comprising chondrocytes (more than 106 cells/mL), thrombin (more than 2 but less than 50 IU/mL), and fibrinogen (20 to 200 mg/mL). The composition further comprises collagen (0.01 to 20 mg/mL).

Passaretti et al. teach a tissue-engineered cartilage composition comprising isolated autologous chondrocytes ($40x10^6$ cells/mL), fibrinogen (80 to 160 mg/mL), and thrombin (50 units/mL (i.e. 50 IU/mL) (abstract; and page 807, paragraphs 3 and 4). The chondrocytes are harvested from cartilage using an enzyme and the cells are incubated in cell media (pages 806-807, chondrocyte isolation section).

Passaretti et al. does not teach the presence of collagen at 0.01 to 20 mg/mL in the disclosed composition.

Liu et al. teach a matrix or the support of cartilage repair in the form of a fibrin-collagen tissue equivalent which comprises 20 mg/mL collagen and 2 U/mL of thrombin combined with 20 mg/mL fibrinogen at 1:1 (columns 14-15, examples 7 and 8). This collagen-fibrinogen-thrombin matrix is a competent support matrix for chondrocytes which are isolated from cartilage (column 5, lines 42-67).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a cartilage therapeutic composition comprising

enzyme-treated, isolated, and cultured autologous chondrocytes, fibrinogen, and thrombin as taught by Passaretti et al. and provide collagen within the fibrinogen-thrombin support matrix as taught by Liu et al. One of ordinary skill in the art would have been motivated to do so because Passaretti et al. teach that a tissue-engineered cartilage comprising a matrix with chondrocytes are appropriate for the clinical application of cell-based therapy (page 814, paragraph 2) and Liu et al. teach that collagen-fibrinogen-thrombin matrices are appropriate matrices for carrying chondrocytes for cartilage repair (column 5, lines 54-67; and column 8, lines 32-41). In light of the forgoing discussion, it would be obvious to one of ordinary skill in the art that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.

Passaretti et al. do not teach that the concentration of thrombin is more than 2 IU/mL but less than 50 IU/mL.

Nevo et al. disclose a composition for the repair of defects in cartilage (col. 1, line 55). The composition comprises chondrocytes, about 5 to 50 U/mL (i.e. IU/mL) of thrombin and fibrinogen (col. 2, lines 27-35). The concentration of thrombin can be on the order of 10 to 50 IU/mL when slow formation of the gel composition is desired or on the order of 20 to 50 IU/mL when a quick setting of the gel is desired (col. 2, lines 43-47).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a concentration of thrombin in the range of greater than 20 but less than 50 IU/mL in the composition of the combined references. The ordinary artisan would have been motivated to do so because Nevo et al. teach that the concentration of thrombin can be adjusted to the need of time of the formation of the gel. This is motivation for someone of ordinary skill in the art to practice or test the parameter values widely to find those that are functional or optimal which then would be inclusive or cover that values as instantly claimed. Absent any teaching of criticality by the Applicant concerning the concentration of thrombin in the claimed composition, it would be prima facie obvious that one of ordinary skill in the art would recognize these limitations are result effective variable which can be met as a matter of routine optimization (MPEP § 2144.05 II).

Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Claims 1, 5 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Passaretti et al. (2001) in view of Nevo et al. (US 4,642,120; new reference) and Liu et al. (US 5,972,385), as applied to claims 1 and 6, in further view of Petito et al. (US 2002/0025921).

Applicant claims a composition comprising chondrocytes (more than 106 cells/mL), thrombin (more than 2 IU/mL but less than 50 IU/mL), fibrinogen (20 to 200 mg/mL) and collagen (0.01 to 20 mg/mL). The composition further comprises an antibiotic or antifungal agent that can be streptomycin.

The combined disclosures of Passaretti et al., Nevo et al. and Liu et al. are discussed supra.

The combined references do not teach the presence an antifungal or antibiotic agent such as streptomycin.

Petito et al. disclose a collagen composition for cartilage repair (abstract; and paragraph 77-78). Petito et al. also the disclose the incorporation of antibiotics such as streptomycin in the composition to enhance the bacteriostatic properties of the composition (paragraphs 94-95 and 102-103).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to provide a cartilage therapeutic composition comprising enzyme-treated, isolated, and cultured autologous chondrocytes, collagen, fibrinogen, and thrombin, at the claimed concentrations, and streptomycin. the ordinary artisan would have been motivated to do so because Petito et al. teach a cartilage repair composition comprising collagen and an antibiotics enhance the bacteriostatic quality of the composition and promote the healing of cartilage (abstract; and paragraphs 2, 77, and 102-103). In light of the forgoing discussion, it would be obvious to one of ordinary skill in the art that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it

is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sue Liu can be reached on 571-272-5539. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Primary Examiner, Art Unit 1653